DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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January 16, 2015

Technolas Perfect Vision Gmbh
% Mr. Ken Nehmer
Senior Manager, Regulatory Affairs
1025 Sanchez Street
San Francisco, California 94114

Re: K141379
Trade/Device Name: Victus Femtosecond Laser Platform
Regulation Number: 21 CFR 886.4390
Regulation Name: Ophthalmic Laser
Regulatory Class: II
Product Code: OOE
Dated: January 9, 2015
Received: January 12, 2015

Dear Mr. Nehmer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Y. Alexander -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose, and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K141379

Device Name
VICTUS Femtosecond Laser Platform

Indications for Use *(Describe)*

"The VICTUS Femtosecond Laser Platform is indicated for use in:

• The creation of a corneal flap in patients undergoing LASIK surgery or other treatment requiring initial lamellar resection of the cornea
• For anterior capsulotomy during cataract surgery
• The creation of cuts / incisions in the cornea in patients undergoing cataract surgery or other ophthalmic treatment requiring cuts / incisions in the cornea."

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

5. 510(k) Summary of safety and effectiveness

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

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Date of Summary: January 9, 2015

Trade Name: VICTUS Femtosecond Laser Platform

Common Name: Ophthalmic Laser

Classification Name: Laser, Ophthalmic

Device Classification: Class II

Product Code OOE (Ophthalmic Femtosecond Laser)
HQF (Laser, Ophthalmic)

Predicate Devices: VICTUS Femtosecond Laser Platform (K132534)

Substantially Equivalent To

510(k) Number	Product Trade Name	Manufacturer
K132534	VICTUS Femtosecond Laser Platform	Technolas Perfect Vision GmbH

SECTION 5 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

Description of the Device Subject to Premarket Notification

The VICTUS Femtosecond Laser Platform (VICTUS) is a precision ophthalmic surgical laser and is cleared for use in the creation of a corneal flap in patients undergoing LASIK surgery or other treatment requiring initial lamellar resection of the cornea and for patients undergoing anterior capsulotomy during cataract surgery (via K120426). In addition, the VICTUS has been cleared for patients undergoing cataract surgery or other ophthalmic treatment requiring penetrating arcuate cuts / incisions in the cornea (K122386) and primary/secondary corneal incisions (K132534). This submission does not add to the indications previously cleared for the VICTUS Platform.

The patient interfaces used for the VICTUS platform remain unchanged from that which was previously discussed and cleared via K132534. For all indications for use, laser pulses are delivered through a sterile disposable Patient Interface, consisting of a contact lens and suction clip to provide suction. The contact lens and suction clip assembly creates a reference surface for depth control and fix the eye relative to the delivery of the laser beam. Surgical effects are produced by scanning thousands of individual pulses, producing continuous incisions. The location of the tissue photodisruption is controlled by a fixed laser beam focused through a scanning optic system to the desired location.

The fundamental scientific technology and indications for use remains the same as previously cleared for the VICTUS Femtosecond Laser Platform under K132534.

Indications for Use

The VICTUS Femtosecond Laser Platform is indicated for use for:

- the creation of a corneal flap in patients undergoing LASIK surgery or other treatment requiring initial lamellar resection of the cornea.
- for anterior capsulotomy during cataract surgery.
- the creation of cuts / incisions in the cornea in patients undergoing cataract surgery or other ophthalmic treatment requiring cuts / incisions in the cornea.

Technical Characteristics Comparison

The design principle of the VICTUS Platform is fundamentally the same as that previously cleared for VICTUS under K132534. The VICTUS Platform mode of operation is the same as that previously cleared for the VICTUS Platform via K132534 which delivers femtosecond pulses to produce a pattern of photodisruption to create cuts / separation in ophthalmic tissue.

The means of fixation of the patient contact portion of the VICTUS Platform is the same as that present in the VICTUS Platform cleared in K132534. The VICTUS Platform uses vacuum to affix a suction ring to the corneal surface prior to use. There is no change to vacuum suction or force pressure related to the patient interface as compared to that previously described and cleared in K132534.
The VICTUS Platform mode of operation and the technology used to create the cutting action are identical to the predicate VICTUS Platform device (K132534), and therefore substantially

equivalent to the legally marketed predicate device.

Performance Data

The VICTUS Femtosecond Laser Platform has undergone testing and is in compliance with applicable safety standards as listed in the following table.

Standard	Title
EN ISO 60601-1	Medical electrical equipment – Part I: General requirements for safety
EN ISO 60601-1-2	Medical electrical equipment – Part 1: General requirements for safety; 2. Collateral standard: electromagnetic compatibility; requirements and tests
EN ISO 60601-2-22	Medical electrical equipment – Part 2: Particular requirements for the safety of diagnostic and therapeutic laser equipment

The VICTUS Femtosecond Laser Platform has been found to perform equivalently to the predicate device. The VICTUS Femtosecond Laser Platform and the predicate device therefore have a similar performance profile.

Non-Clinical Performance Data

A variety of test procedures were conducted to demonstrate that the performance of the modified VICTUS Platform remains substantially equivalent to that previously cleared in K132534. The collected data were evaluated by comparing the mean values to the specified acceptance criteria and their 95% confidence intervals. Four different materials were used for the bench performance testing: porcine eyes, agarose gel, polyethylene terephthalate (PETG), and polymethyl methacrylate (PMMA). The acquired test data successfully verified that the various parameters meet their pre-defined acceptance criteria.

Clinical Performance Data

An open, controlled, multi-surgeon, single-center clinical study was performed to confirm the intraoperative accuracy of biometry visualization performed by VICTUS optical coherence tomography (OCT) and its comparability with LENSTAR LS 900 by means of axial optical resolution accuracy comparison. Two groups of patients from two clinical applications i.e. femtosecond-laser flap creation (flap group – 58 eyes) and femtosecond laser assisted cataract surgery (cataract group – 113 eyes) were observed in this study. All 113 and 58 eyes assigned in the femto-cataract and flap group, respectively were available for a retrospective analysis of the correlation and agreement of the biometric data for lens thickness, anterior chamber depth (ACD) and central cornea thickness (CCT). The lens thickness, ACD and CCT measured by VICTUS OCT were compared with LENSTAR LS900 and the results are consistent.

All the enrolled cataract patients were treated with femtosecond laser assisted capsulotomy before the femtosecond laser assisted lens fragmentation by VICTUS femtosecond laser platform. The cataract group (113 eyes) represented cataract grades I through IV (Grade I = 76, Grade II = 16, Grade III = 16, Grade IV = 5). All laser assisted capsulotomy procedures were completed fully using the VICTUS laser platform with no need for manual intervention to complete the capsulotomy. There were no adverse or serious adverse events reported by the investigators during the clinical study. In addition, there were no device malfunctions which led or potentially led to adverse or serious adverse events.

Basis for Determination of Substantial Equivalence

The technological characteristics of the VICTUS Platform are substantially equivalent to the technological characteristics of the predicate VICTUS Platform which was cleared via K132534.

The indications for the VICTUS Platform remain unchanged from those cleared via K132534.